

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims of this application:

Listing of Claims:

1. (currently amended) A multi-particulate pharmaceutical dosage form of a skeletal muscle relaxant providing a modified release profile comprising a population of extended release beads,

wherein said extended release beads comprise

an active-containing core particle comprising a skeletal muscle relaxant selected from the group consisting of cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof; and

an extended release coating comprising a water insoluble polymer membrane surrounding said core,

wherein said dosage form when dissolution tested using United States Pharmacopoeia Apparatus 2 (paddles @ 50 rpm) in 900 mL of 0.1N HCl at 37°C exhibits a drug release profile substantially corresponding to the following pattern:

after 2 hours, no more than about 40% of the total active is released;

after 4 hours, from about 40-65% of the total active is released; and

after 8 hours, from about 60-85% of the total active is released; and

~~after 12 hours, from about 75-85% of the total active is released;~~

wherein said dosage form provides therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions when administered to a patient in need thereof.

2. (previously presented) A pharmaceutical dosage form as defined in claim 1, wherein said skeletal muscle relaxant comprises cyclobenzaprine hydrochloride.
3. (previously presented) A pharmaceutical dosage form as defined in claim 2 wherein said pharmaceutical dosage form provides a maximum blood plasma concentration (C_{\max}) within the range of about 80% to 125% of about 20 ng/mL of cyclobenzaprine HCl and an AUC_{0-168} within the range of about 80% to 125% of about 740 ng·hr/mL and a T_{\max} within the range of 80% to 125% of about 7 hours following oral administration of a single 30 mg cyclobenzaprine HCl MR Capsule.
4. (original) A pharmaceutical dosage form as defined in claim 3 wherein the adjusted mean ratio of CMR 30 mg/CMR 15 mg is greater than about 2 for each of AUC_{0-168} ($p < 0.001$), $AUC_{0-\infty}$ ($p < 0.001$), and C_{\max} ($p < 0.001$).
5. (previously presented) A pharmaceutical dosage form as defined in claim 1 further comprising an immediate release bead population, wherein said immediate release beads comprise an active-containing core particle comprising a skeletal muscle relaxant and said immediate release beads when tested in a USP Type 2 Apparatus at 50 rpm in 900 ml 0.1 N HCl at 37°C release at least about 70% of the active within 30 minutes.
6. (original) A pharmaceutical dosage form as defined in claim 1, wherein said dosage form comprises only one extended release bead population.
7. (original) A pharmaceutical dosage form as defined in claim 1, wherein said water insoluble polymer is selected from the group consisting of ethers and esters of cellulose, pH-insensitive ammonio methacrylic acid copolymers, and mixtures thereof.
8. (original) A pharmaceutical dosage form as defined in claim 7, wherein said extended release coating further comprises a plasticizer.
9. (original) A pharmaceutical dosage form as defined in claim 8, wherein said plasticizer is selected from the group of triacetin, tributyl citrate, tri-ethyl citrate, acetyl tri-n-butyl citrate,

diethyl phthalate, dibutyl sebacate, polyethylene glycol, polypropylene glycol, castor oil, acetylated mono- and di-glycerides and mixtures thereof.

10. (original) A pharmaceutical dosage form as defined in claim 1, wherein said water insoluble polymer membrane on the drug cores comprises from about 7% to 12% by weight of the coated beads.

11. (original) A pharmaceutical dosage form as defined in claim 7, wherein said extended release coating further comprises a water soluble polymer selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene glycol polyvinylpyrrolidone and mixtures thereof.

12-23. (canceled)

24. (previously presented) A pharmaceutical dosage form as defined in claim 1, wherein said skeletal muscle relaxant comprises cyclobenzaprine.

25. (new) A pharmaceutical dosage form as defined in claim 1, wherein said drug release profile substantially corresponds to the following pattern:

after 2 hours, no more than about 40% of the total active is released;

after 4 hours, from about 40-65% of the total active is released;

after 8 hours, from about 60-85% of the total active is released; and

after 12 hours, from about 75- 85% of the total active is released.